REMARKS

Claim 26 is currently pending and stands rejected. Claim 26 is amended and claims 27-39 are added herein. Support for the present claim amendment can be found throughout the application and claims as originally filed. Support for the new claims can also be found throughout the application and claims as originally filed, for example, support for new claim 27 can be found *inter alia* at page 8, lines 1-9. Support for new claim 28 can be found *inter alia* at page 8, lines 1-9; page 11, lines 4-16, 23-28 and page 17, lines 14-18. Support for new claim 29 can be found *inter alia* at page 8, lines 4-9. Support for new claim 30 can be found *inter alia* at page 8, lines 1-9. Support for new claims 31 and 32 can be found *inter alia* at page 11, lines 23-28; page 13, lines 17-24. Support for new claim 33 can be found *inter alia* at page 6, lines 7-28; page 8, lines 1-9; page 9, line 24 to page 10, line 5; page 11, lines 23-28. Support for new claims 34 and 35 can be found *inter alia* at page 8, lines 1-9, 26-30, and page 11, lines 11-16, 20-28. Support for new claims 36 and 37 can be found *inter alia* at page 13, lines 17-24; page 11, lines 23-28. Support for new claim 38 can be found *inter alia* at page 7, lines 16-30. Support for new claim 39 can be found *inter alia* at page 6, lines 7-28; page 8, lines 1-9; page 9, line 24 to page 10, line 5; page 11, lines 23-28. Support for the present amendments to the specification can be found *inter alia* in the specification at page 8, lines 1-9; page 11, lines 4-16, 23-28. Entry of the present amendment is respectfully requested. No new matter is presented.

Drawings

The Office has objected to the drawings under 37 CFR § 1.83(a). The Office has specifically requested the depiction of desiccant material in a Figure. Accordingly, the Applicants hereby provide updated Figure 2 for consideration by the Office. Importantly, the shape and form of the desiccant is provided solely for ease of illustration and represents but one embodiment, as such, the moisture absorbing chemical need not be provided in the shape or form depicted in updated Figure 2. Furthermore, based on the present disclosure, one of skill in the art would understand that the desiccant material need not be represented by an element requiring separate illustration. For example, the desiccant could line/coat the device or be provided as a part of the device housing or support itself.

Rejection Under 35 U.S.C. § 112, Second Paragraph

Claim 26 stands rejected under 35 U.S.C. § 112, second paragraph as purportedly indefinite. The Office has specifically indicated that the preamble requires a more detailed description of the prior art immunoassay device. Claim 26 is amended herein to further describe the claimed device. Respectfully, the Applicants assert that a sufficiently detailed description is set forth because the Jepson claim format merely requires a general description of the required elements. *See* 37 C.F.R. § 1.75(e)(1). Present claim 26 indicates that an immunoassay is provided having a housing that allows for the introduction of liquid sample, a porous matrix material and at least one immunological reagent in dried form.

Double Patenting Rejection

The Office has rejected claim 26 under the judicially created doctrine of obviousness-type double patenting as purportedly not patentable over claim 1 of U.S. Patent No. 5,763,262 (the '262 patent). Respectfully, the Applicants assert that a terminal disclaimer under 37 CFR 1.321(c) will be provided upon the indication of allowable subject matter. Accordingly, as this rejection relates to form not necessary for further consideration of the present claims, applicants respectfully request that the Office hold this requirement in abeyance until allowable subject matter in this application is indicated. See 37 C.F.R. § 1.111(b).

Rejections Under 35 U.S.C. § 103(a)

Claim 26 stands rejected under 35 U.S.C. § 103 as purportedly obvious over Tom et al, U.S. Patent No. 4,366,241 (*Tom*) in view of Svoboda et al. U.S. Patent No. 4,017,261 (*Svoboda*) and Thomas et al. U.S. Patent No. 4,330,627 (*Thomas*). The Applicants have considered the Office's assertions together with the teachings of *Tom* in view of *Svoboda* and *Thomas*, and respectfully disagree with the Office's position. Specifically, the Applicants herein assert that there is a lack of motivation to make the asserted combination of references.

As indicated by the Federal Circuit, there must be some motivation, suggestion, or teaching of the desirability of making the specific combination that was made by the applicant. *See, e.g., In re Dance* 48 USPQ2d 1635, 1637 (Fed. Cir. 1998). Requisite motivation requires a desirable combination of references rather than a combination of what is feasible. *See Winner Int'l Royalty Corp. v. Ching-Rong Wang*, 53 USPQ2d 1580, 1587 (Fed. Cir. 1990) (emphasis). "Although a

reference need not expressly teach that the disclosure contained therein should be combined with another, the showing of combinability, in whatever form, must nevertheless be 'clear and particular.'" *Id.* at 1586-87 (quoting *In re Dembiczak*, 175 F.3d 994, 999, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999) (citations omitted). The suggestion or motivation may be derived from the prior art reference itself, from the knowledge of one of ordinary skill in the art, or from the nature of the problem to be solved. *See Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.*, 37 USPQ2d 1626, 1630 (Fed. Cir. 1996). However, as cautioned in *In re Rouffet*, if the knowledge of those of ordinary skill in the art is relied upon, the notoriety of the particular references used to render the claims obvious should be accounted for in order to avoid a hindsight based analysis. *In re Rouffet*, 47 USPQ2d 1453, 1456 (Fed. Cir. 1998). Accordingly, "the examiner must show reasons that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed." *Id.* (emphasis added).

The motivation set forth by the Office in the present rejection appears to be that

> [i]t would have been obvious to one of ordinary skill in the art to include a desiccant in the housing of the immunoassay device of Tom et al, as taught by Thomas et al, because Svoboda et al teach that a desiccant would provide the advantage of retarding deterioration of reagent containing test strips prior to their use.

July 23, 2004 Office action at page 6.

The primary reference, *Tom*, appears to teach a method and apparatus for performing immunoassays having two principal parts, an immunosorbing zone and a liquid absorbing zone. *See* col. 14, lines 33-37. *Tom* further contemplates closing the area around the immunosorbing zone to prevent sample or other reagent solution from contacting the liquid absorbing zone using an enclosure. *See* col. 15, lines 27-33. The enclosure often comprises sheets of material adhered to one another and can incorporate an air opening to prevent the entrapment of air to allow fluid flow through the assay. *See* col. 17, lines 45-46, 61-66; col. 18, lines 15-26. Notably, *Tom* does not appear to describe a true housing as currently contemplated. *Tom* apparently seeks to solve the problem of cumbersome laboratory-restricted immunoassays by providing a convenient assay that can be utilized by untrained personnel, and which produces reliable results regardless of the manner

in which the assay is utilized. *See* col. 2, lines 36-58. *Tom*, however, bears no mention of the desirability of providing a desiccant material in its devices to avoid the detrimental effects of moisture accumulation. Importantly, *Tom* fails to mention that moisture presents a problem to its assays or immunoassays in general whatsoever. As such, *Tom* fails to provide an indication about the benefits of the incorporation of a desiccant material in its devices. Furthermore, Tom provide no indication about how its devices should be modified to successfully incorporate a desiccant. The fluid flow characteristics of *Tom's* devices are important for the performance of the assay, however, no indication is provided regarding how *Tom's* devices would be modified to incorporate a desiccant material in the devices while maintaining the requisite flow characteristics. Importantly, the required modification would be considerable, even if a suggestion to incorporate a desiccant within the enclosure of *Tom* were provided. As such, given the required characteristics pf *Tom's* devices, it is unknown how one of skill in the art would adapt these devices to incorporate a desiccant (as indicated, *Tom* does not appear to teach a true housing).

Accordingly, *Tom* clearly provides no suggestion or motivation to incorporate a desiccant material in an immunoassay device, much less that a moisture-related problem with its immunoassays exists at all. Therefore, it would seem that the knowledge of one of ordinary skill in the art must form the basis for the combination currently set forth by the Office of *Tom* with the secondary references (*Svoboda* and *Thomas*) to improve a device that has not indicated that a moisture problem exists. In light of *Rouffet*, the next inquiry requires casting the mind back to the time of the present invention and evaluating the principle, supposedly known to one of ordinary skill in the art, which suggests the asserted combination; while taking account of the notoriety of the secondary references. The principle, of course, was not set forth or alluded to in *Tom*. Thus, as described below, the attempted combination with *Svoboda* and *Thomas* fails in that *Tom* denies the presence of moisture as a problem, thus one of skill in the art would not have been motivated to look to *Thomas* or *Svoboda* for guidance. Further, *Thomas* relates to a different type of testing device than *Tom's* device and provides a desiccant for a completely different purpose than the present claims. *Svoboda* also relates to a different type of testing device than *Tom* and utilizes a desiccant as a subsidiary stabilizing means to maintain its unstable reagents in packaging materials. As such,

assuming *arguendo* that a motivation was set forth in *Tom*, one of skill in the art would not look to *Thomas* and/or *Svoboda* for guidance.

Svoboda provides chemical assays for evaluating the presence of blood and hemoglobin in urine. *Svoboda* seeks to solve the problem of premature oxidation of the unstable chemical reagents necessary for the chemical assay and to improve on the prior attempts at solving this problem. In general, the *Svoboda* devices are simple one-piece devices comprising impregnated filter paper cut into strips. *See Svoboda* Examples. *Svoboda* provides a combination of acid buffer having a specific pH, a chromogen, a wetting agent, an organic hydroperoxide, a solid salt, a solid film-forming material, and an agent capable of enhancing the peroxidase activity of hemoglobin, each of which is disposed on a bibulous carrier. *See* col. 2, lines 33-44. The "critical feature" of the *Svoboda* invention apparently lies "in the proper segregation of the acid buffer and chromogen from the organic peroxide salt and the organic amine" to avoid premature oxidation. *See* Col. 3, lines 64-66. As indicated by the Office, *Svoboda* provides that deterioration of reagents may be precluded by storing the "test strips in closed containers in the presence of a desiccant such as silica or a molecular sieve." Col. 4, lines 56-59. The Office particularly points to this section of *Svoboda* for the "suggestion" "that a desiccant would provide the advantage of retarding deterioration of reagent containing test strips prior to their use." Based on the configuration of the *Svoboda* devices as simple slices of filter paper, the "closed container" necessarily comprises packaging material from which a device is removed prior to use. Moreover, based on the chemical reagents utilized in the *Svoboda* devices and their intended improvement on the prior art, the avoidance of premature oxidation of reagents potentially induced, in part, by ambient humidity was a concern that led to the unique combination of chemical reagents set out in *Svoboda*. Thus, the issue regarding whether the devices are stored together with a desiccant or molecular sieve is a subsidiary issue versus the main problem to which *Svoboda* set out to solve. Moreover, not only does *Svoboda* not mention that the desiccant can be incorporated in its devices; it also bears no mention of whether a desiccant or molecular sieve could successfully be utilized together with immunoassay reagents. Thus, the motivation to "improve" the devices of *Tom* is not found in *Svoboda* either.

Accordingly, as *Svoboda* describes non-immunoassay test strips and focuses on a unique combination of reagents to avoid oxidation (including the detrimental effects of ambient humidity on the key reagents in blood/hemoglobin chemical assays) of its unstable chemical reagents, it is

asserted that one of skill in the art would not look to *Svoboda* for the teaching that a desiccant could be incorporated in the devices of *Tom* (assuming *arguendo* that Tom had addressed a similar problem). With regard to the present invention, the principle underlying the means of achieving reagent stability are completely different, and *Svoboda*, as a non-analogous art reference, would not have held the requisite notoriety to one of skill in the art of immunoassays. Nevertheless, if one of skill in the art looked to the passage indicated by the Office in *Svoboda*, he/she would find information in line with what was generally known about the nature of desiccants and molecular sieves and, in addition, that such materials can be incorporated in the packaging of the *Svoboda* chemical reagent based blood/hemoglobin assay to help maintain its unstable reagents. Moreover, as *Svoboda* fails to mention the use of a desiccant together with an immunoassay, it is clear that experimentation would be required to determine whether a desiccant/molecular sieve could be incorporated together in the packaging of an immunoassay device with any expectation of success.

Thomas describes a testing tray for the purpose of biochemical identification of microorganisms which may be present in biological samples such as blood or urine. The sample is first incubated in order to develop a detectable culture of microorganisms. The testing tray defines a number of separate test chambers or channels 16, one for each of the tests to be performed. At least one reagent paper which will or will not change color depending on whether the given test is positive or negative is disposed in each of the test channels. It is stated in col. 1, lines 53-58, that the testing trays are usually packed in a sealed envelope and that problems have been caused by unwanted moisture developing in the testing channels due to condensation. In order to solve this problem a desiccant 82 is provided within a separate chamber 80 within the body of the testing tray, the desiccant 82 communicating with each of the test channels 16 via a desiccant channel 84. The desiccant supposedly keeps the housing channels dry thus facilitating fluid flow. The purpose of the desiccant is not to dry the reagent disk, but rather, to dry the channels.

Thomas does not disclose nor suggest an immunoassay device. Moreover, the desiccant provided in *Thomas* serves a different purpose from the desiccant employed in the *Svoboda* packaging or in the device of the present invention. *Thomas* seeks to solve the problem of condensate moisture in the housing channels. Condensate in the channels would tend to block them and interfere with fluid flow in the channels. The desiccant keeps the housing channels dry thus facilitating fluid flow. This is made clear even in claim 1, which states that a desiccant element may

be placed within the desiccant chamber "to extract undesired moisture from each said testing channels prior to the use of the tray." Col. 7, lines 16-18.

The principle underlying the use of a desiccant in *Thomas* is completely different from the present invention. Moreover, as a non-analogous biochemical testing tray for identifying microorganisms, *Thomas* would not have held the requisite notoriety to one of skill in the art such that one would look to this reference for a teaching about the use of a desiccant in an immunoassay.

Based on the foregoing, several points weigh against the asserted combination of *Tom* with *Thomas* and *Svoboda* to render the present claims obvious. First of all, *Tom* provides no indication that a moisture problem exists. Second, *Thomas* and *Svoboda* represent non-analogous art to that of *Tom*. Third, none of the cited references (nor the general knowledge in the art) clearly and particularly indicate that the combination set forth by the office represents a desirable combination. Fourth, if one of skill in the art looked to the non-analogous *Svoboda* and *Thomas* disclosures, he/she would merely find, at most, an invitation to experiment with means to stabilize chemical reagents or keep fluid flow channels clear of condensate. Accordingly, a sufficient suggestion or motivation for the present combination of references set forth by the Office does not exist (in the cited references or otherwise without reference to the present disclosure) and the present rejection may be properly withdrawn.

Thomas in view of Tom

Claim 26 further stands rejected under 35 U.S.C. § 103 as purportedly obvious over *Thomas* in view of *Tom*. In this rejection the Office utilizes *Thomas* as the primary reference. The Office specifically indicates that

> [i]t would have been obvious to one of ordinary skill in the art to use the immunological reagents for detection of microorganisms of Tom et al in the reagent disks in the tray of Thomas et al because Thomas et al teach using the tray for detection of microorganisms and Thomas et al does not place any limitations on what reagents can be used in the reagent disks. Moreover, the antibodies taught by Tom et al are highly specific binding reagents which provide the advantage of a more sensitive tray for detection of microorganisms.

July 23, 2003 Office action, pages 6-7. Respectfully, the mere lack of explicit limitations on the type of reagents that supposedly can be utilized in *Thomas* does not seem to set forth the proper standard for a combination of references under 35 U.S.C. § 103. As set forth hereinbefore, a suggestion or motivation (which must be both desirable and clear and particular) must be present to combine isolated disclosures.

Clearly *Thomas* does not suggest the inclusion of immunological reagents, much less how an assay would proceed utilizing immunological reagents to obtain meaningful results. It would seem that extra steps or aspects would be required to reconfigure *Thomas* into an immunoassay (*i.e.*, to incorporate the multiple steps/reagents required to produce a detectible signal utilizing the reagents of *Tom*, *see Tom* col. 5, line 51 to col. 6, line 12) that are not taught nor suggested by *Thomas*. Moreover, *Thomas* teaches a closed system having an opening useful for the introduction of liquid sample. The system is closed, in part, to avoid exposing the user to potentially harmful microorganisms and to permit an adequate chemical reaction to take place. *See, e.g.*, col. 5, line 37 to col. 6, line 27. In contrast, *Tom* teaches an open system requiring an air opening required to permit fluid flow through the system, and at the desired rate. *See, e.g.*, col. 17, line 45 to col. 18, line 27. Thus, although no guidance is provided in *Tom* or *Thomas*, it is clear that significant alteration of the *Thomas* device would be required to provide an immunoassay.

Furthermore, the indication by the Office that the antibodies of *Tom* are highly specific is not determinative as *Thomas* does not indicate that its reagents yield inaccurate results, nor that more specific reagents are desired. Indeed, *Thomas* appears specifically geared to the use of biochemical reagents. The specially treated reagent discs generally change color upon contact with a fluid sample via a chemical reaction, depending on whether an analyte of interest is present. The required characteristics to make use of the *Tom* reagents such as particular sample flow characteristics through the reagent discs, and/or reagents introduced in multiple steps are not contemplated nor required to generate detectible results in *Thomas*. Moreover, neither *Thomas* nor *Tom* indicate that immunological reagents can be safely and successfully incorporated in a device together with a desiccant; and as *Thomas* appears to require a desiccant to keep condensate from forming within the test channels, further indication is provided that immunological reagents are not compatible with the *Thomas* device without significant alterations. Based on the foregoing, the Applicants respectfully assert that the requisite suggestion or motivation to combine *Tom* with *Thomas* is not set forth in the

specific references, nor in the nature of the problem to be solved, nor in the knowledge of those skilled in the art. Accordingly, the Applicants respectfully request withdrawal of this rejection. Moreover, one of skill in the art would not appear to be motivated to look to the non-analogous *Tom* reference to solve the condensate problem of *Thomas* and thereby incorporate immunological reagents. Accordingly, the Applicants respectfully request withdrawal of this rejection.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 273102008104.

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Respectfully submitted,

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